

UNDERSTANDING JAPAN'S COSMETIC REGULATIONS



Marie MAGNAN

Regulatory Affairs Manager,
COSMED



1



LOBBYING FOR COSMETIC COMPANIES

- French National Agency for Medicines and Health Products Safety (ANSM)
- European Commission
- ISO, CEN, AFNOR
- Foreign countries authorities

SHARED SERVICES

- Regulatory watch : 120 countries monitored
- Free Sale Certificates : <https://www.cosmedcvl.fr/>
- Training
- Purchasing group
- Events, Congress




2

YOUR WORLDWIDE REGULATORY MONITORING

 **120** Countries monitored (Europe & international).
On-line available databases 24 hours, 7 days

 **1500** Updated factsheets and summary tables

 **48h** Deadline answer to your regulatory requests from a specialized team

 **7 days a week** Email alerts at each regulatory amendment



Updated database - Experts assistance

 **CHOOSE** your tailored solution
1 database France / Europe OR International
2 databases France / Europe AND International

EUROPEAN DATABASE	INTERNATIONAL DATABASE
<ul style="list-style-type: none"> . French and E.U regulations . Specificities of E.U . Summary Tables of regulated ingredients . Product Information File . Assessment of ingredients . Notification of cosmetic product . Labelling, Claims . Cosmetovigilance . PAO tool . REACH, CLP . Actors' Obligations ... 	<ul style="list-style-type: none"> . Classification of products: cosmetics, quasi-drugs, OTC, Natural Products . Fact sheets on regulations . Summary tables of regulated substances . Labelling, Claims . Registration / Notification of products Comparative substances tables (UV filters ...)

 **NEW** COSMED REGULATORY monitoring in english
A real asset for foreign subsidiaries and / or distributors



3

JAPAN – Market data



SUSTAINABILITY / GUILT-FREE
HEALTHY **CONVENIENCE**
SCIENCE COSMETICS **BOTANICAL**
CONFORTABLE **CLEAN BEAUTY**
SAFETY

23,5 Mds Dollars in 2019
 3rd market after the USA and China
 Weak growth
 Nearly saturated market
 High competition

Opportunities for growth

- Cosmetics for men : 4,8% and still growing
- « All in one » products / sensitive skin products
- Products with demonstrated efficacy
- High demand for anti aging, organic, natural, functional cosmetics

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4

TABLE OF CONTENTS

General – Product Categories

Focus Quasi-drugs

Ingredients

Labelling – Claims

Importation – Other information

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5

General

Competent authorities

- Ministry of Health, Labour and Welfare (MHLW)
- Pharmaceuticals and Medical Devices Agency (PMDA)
- Japan Cosmetic Industry Association (JCIA)

Main regulatory texts

Pharmaceutical and Medical Device Law
Standards for Cosmetics

Cosmetic products

Marketing without notification nor registration



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6

Product categories

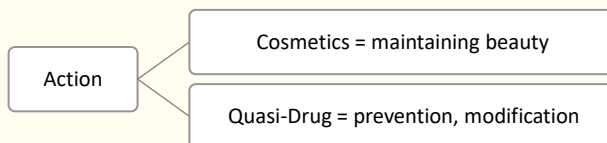


Article 2.3 of the Pharmaceutical Affairs Law

The term "cosmetic" used in this law refers to articles with **mild action on the human body**, which are intended to be applied to the human body through rubbing, sprinkling or other similar methods, aiming to clean, beautify and increase the attractiveness, alter the appearance or to keep the skin or hair in good condition

Cosmetic products (meaning as beauty products) = 2 different product categories in Japan

- Cosmetics
- Quasi-drugs, which are products containing an active ingredient with a weak but real pharmacological activity on the human body (while not falling into the category of drugs)



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7

TABLE OF CONTENTS

General – Product Categories

Focus Quasi-drugs

Ingredients

Labelling – Claims

Importation – Other information



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8

Focus Quasi-Drugs

Quasi-drugs (non-exhaustive)

Anti-dandruff
 Whitening
 Anti-acne
 Anti-bacterial
 Anti-chapping
 Against drought
Medicated soaps
Hair care
 Deodorant
 Anti-perspirant
 Product for hair regrowth
Hair dyes
Perm products
Toothpaste
Bath salts
Products for breath
Oral care



Cosmetics may fall in the quasi-drugs category depending on ingredients, claims...

- ⇒ Pharmaceutical ingredient
- ⇒ Lexical field for claims
- ⇒ Claims not permitted for cosmetics

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9

Focus Quasi-Drugs



▪ ACTIVE + EXCIPIENTS

Excipients: subject to positive ingredient list or possibility to use new excipient(s)

Actives: list of recognized actives or possibility to use a new actives

Colorants: id. cosmetics

- Pre-Marketing Registration and Approval (PMDA)
- Comprehensive documentation for active ingredient
- Complete verification of product and claimed effects
- Possibility of following a monograph for some products
- Specific labelling (term "quasi-drug" mandatory)

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10

TABLE OF CONTENTS

General – Product Categories

Focus Quasi-drugs

Ingredients

Labelling – Claims

Importation – Other information

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11

Ingredients

Regulated by the Safety Standard for cosmetics:

- Prohibited substances
List in annex of Standard for Cosmetics (30 substances) +
Class I and II lists of the CSCL (Japanese REACH-like
regulation) + Poisonous and Deleterious Substances
Control Act
- Restricted substances
- Authorized preservatives
- Permitted UV filters (positive list of UV absorbers only)



Positive list for dyes :

Order No. 30 of 31 August 1966 for tar-based dyes

Other types of dyes (natural...) considered as normal ingredients

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12

Ingredients

Other ingredients:

"The ingredients of cosmetic products, including the impurities they contain, must not contain anything that could cause infection or make the use of cosmetic products hazardous to health" - Standard for Cosmetics



- under the responsibility of the company responsible for putting on the market
- security check
- should not be considered as pharmaceutical (ingredients with medicinal effect or listed in the Japanese pharmacopoeia)

List of "pharmaceutical" substances authorized in cosmetics

MHLW (Ministry of Health, Labour and Welfare) notification n°0524001 - May 2004

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13

TABLE OF CONTENTS

General – Product Categories

Focus Quasi-drugs

Ingredients

Labelling – Claims

Importation – Other information



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14

Labelling of cosmetic products

- Name and Address of Marketing License Holder
- Product name
- Batch number
- Net weight
- List of ingredients (Japanese INCI)
- Expiry date for cosmetics specified by MHLW announcement
- Precautions for use, instructions for use
- Country of origin

=> Labeling in Japanese

Voluntary standards: "Codes on Fair Competition regarding the representations of cosmetics" on labelling and claims, which are widely observed in Japan

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15

Cosmetic claims

Act Against Unjustifiable Premiums and Misleading Representations

Prohibited :

- false, misleading or extravagant statements,
- Assigning unprovable properties to the product
- Claims associated with quasi-drugs or drugs for cosmetics



List of 56
accepted
efficacy
claims for
cosmetics

1	Cleansing hair and scalp	38	Impart fragrance
2	Using fragrance to reduce unpleasant hair and scalp odors	39	Protect nails
3	Keep hair and scalp healthy	40	Keep nails healthy
4	Give moisture and sheen to hair	41	Moisten nails
5	Moisturize hair and scalp	42	Prevent chapped lips
6	Keep hair and scalp moist	43	Improve the texture of the lips skin
7	Make hair supple	44	Moisten lips
8	Make hair easier to brush	45	Keep lips healthy
9	Keep hair lustrous	46	Protect lips, prevent dryness
10	Give luster to hair	47	Prevent lip roughness caused by dryness
11	Stop dandruff and itching	48	Make lips smooth
12	Control dandruff and itching	49	Prevent cavities (by brushing teeth with toothpaste)
13	Supplement and maintain hair moisture and oil content	50	Whiten teeth (by brushing teeth with toothpaste)
14	Prevent hair breakage and frizzing	51	Remove plaque (by brushing teeth with toothpaste)
15	Improve and maintain hair pattern	52	Cleanse the mouth (toothpaste)
16	Prevent hair static electricity	53	Prevent bad breath (toothpaste)
17	Cleanse skin (by removing dirt)	54	Remove tar from teeth (by brushing teeth with toothpaste)
18	Prevent blemishes and rashes (by cleansing – facial wash)	55	Prevent tar deposits (by brushing teeth with toothpaste)
19	Condition skin	56	Reduce the appearance of fine lines caused by dryness
20	Condition the texture of the skin		
21	Keep the skin healthy		
22	Prevent skin roughness		
23	Firm the skin		
24	Moisten the skin		
25	Supplement and preserve skin moisture and oil content		
26	Keep skin supple		
27	Protect the skin		
28	Prevent skin dryness		
29	Soften skin		
30	Provide the skin with tension		
31	Give luster to skin		
32	Make skin smooth		
33	Make beards easier to shave		
34	Condition skin after shaving		
35	Prevent heat rashes (powder)		
36	Prevent sunburn		
37	Prevent skin blotches and freckles resulting from sunburn		

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16

TABLE OF CONTENTS

General – Product Categories

Focus Quasi-drugs

Ingredients

Labelling – Claims

Importation – Other information

Marie MAGNAN – Regulatory Affairs – JAPAN – 23/9/2021



17

Importation

Japanese importer's responsibilities:

- Quality and safety of cosmetics
- Evaluate production management and quality control of cosmetics
- Keep all reports on these products for 5 years
- Establish a system capable of providing reliable information to respond to consumers (queries, quality complaints, product withdrawals, etc.)
- Report a safety issue within 30 days to MHLW

Marketing License: authorizes the importer to put cosmetics on the market

Manufacturer's License: if the final packaging, the labelling in Japanese or the storage of a cosmetic product is done on Japanese soil



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18

Other information

Good Quality Practices (GQP) - Importer (MAH)

- ⇒ To maintain the quality of the products marketed
- ⇒ Product quality control
- ⇒ Defects treatment / Removal
- ⇒ Documentary archive (5 years)

ISO 22716 standard

Good Manufacturing Practices in Cosmetics

- ⇒ Recognized in Japan
- ⇒ A GMP certificate will be requested at import

ISO 16128 standard

Natural and organic cosmetic ingredients

- ⇒ Recognized in Japan



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19

CONCLUSION

Positioning

- ⇒ Product category
- ⇒ Claims
- ⇒ Ingredients / actives



Marketing

- ⇒ Cosmetics: free marketing
- ⇒ Quasi-drugs: approval from authorities

Export

- ⇒ Labelling
- ⇒ Quality

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20



Thank you for your attention

